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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,326	03/04/2002	Tony E. Godfrey	010211	5534
26285	7590	02/10/2005	EXAMINER	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP			WILDER, CYNTHIA B	
535 SMITHFIELD STREET			ART UNIT	
PITTSBURGH, PA 15222			PAPER NUMBER	
			1637	
DATE MAILED: 02/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,326

Applicant(s)

GODFREY ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35,37-53,59-61,63-66 and 78-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59-61,63-66 and 78-86 is/are allowed.
- 6) ☒ Claim(s) 1,2,7,9,14,18,28,30,32,33,41,42 and 46 is/are rejected.
- 7) ☒ Claim(s) 3,4,6,8,10-17,19-27,31,34,35,37-40,43-45 and 47-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All. b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed on November 8, 2004 is acknowledged and has been entered. Claims 4, 19, 35, 37 have been amended. Claims 5, 36, 54-58, 62, 67-77, 87-104 have been canceled. Claims 1-5, 6-35, 37-53, 59-61, 63-66, 78-86 are pending. All of the arguments have been thoroughly reviewed and considered moot in view of the new grounds of rejection based on updated search of the instant invention. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejection under 35 USC 112 second paragraph directed to claims 1-59, 82, 83 and 85 are withdrawn in view of Applicant's amendments and arguments.

New grounds of Rejections

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 7, 9, 14, 18, 30, 32, 33, 41, 42 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al (US 5985552, November 16, 1999). Regarding claim 1, 9, 30, and 32 Howell et al teach a method comprising the step of conducting a PCR amplification on a DNA sample in a PCR reaction mixture, wherein the PCR amplification is conducted in a first

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amplification stage and second amplification stage, each amplification stage comprising one or more PCR cycles and each PCR cycle comprising a denaturing step, an annealing step and an elongation step that *may be* conducted, wherein the PCR amplification of the second amplification stage is conducted under different reaction conditions than the PCR amplification of the first amplification stage (col. 23, line 22 through col. 24, line 16).

Regarding claim 2, Howell et al teach wherein the second primer set is added to the reaction mixture at the beginning of the second amplification stage prior to the steps of denaturing, annealing and elongation (col. 24, lines 5-11).

Regarding claim 7, 33, Howell et al teach the method of claim 1, wherein the reaction mixture comprises a DNA sample, the first primer set having a first effective T_m and the second primer set having a second effective T_m different from the first effective T_m , wherein the annealing step of the first amplification stage is conducted at a different temperature than the annealing step of the second amplification stage and further wherein the effective T_m are about at least a 5 degrees differs between the two stages ((col. 23, line 22 through col. 24, line 16).¹

Regarding claim 14 and 42, Howell et al teach a method of claim 14, wherein a reverse transcription reaction on an RNA sample prior to the first amplification stage, and prior to the addition of PCR primers and thermostable DNA polymerase to the reaction mixture to produce the DNA of the DNA sample of the reaction (col. 23, lines 45-48).

Regarding claims 18 and 46, Howell et al teach the method of claim 1, wherein an internal Positive control DNA is added to the PCR reaction mixture. Note* Howell et al teaches wherein

¹ The T_m was calculated by the examiner using the following formula:
 $T_m (^{\circ}\text{C}) = 2x (A + T) + 4x (G + C).$

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the primer Vβ16mer, which is predicted to bind to 85% of human TCR beta chain genes at all 16 residues and 95% at 15 residues is added to the PCR reaction (col. 23, lines 10-54).

Regarding claim 41, Howell et al teach the method of claim 30, wherein the annealing step of the first amplification stage is conducted at a temperature less than the annealing step of the second amplification stage (col. 24, lines 1-11). Therefore, Howell et al meets the limitations of claims 1, 2, 7, 9, 14, 18, 30, 32, 33, 41, 42 and 46 of the instant invention.

6. Claims 1, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Durmaz et al. (Journal of Microbiological Methods, vol. 29, pages 69-75). Regarding claims 1 and 28, Durmaz et al teach a method comprising the step of conducting a PCR amplification on a DNA sample in a PCR reaction mixture, wherein the PCR amplification is conducted in a first amplification stage and a second amplification stage each stage comprising one or more PCR cycles and each PCR cycle comprising a denaturing step, an annealing step and an elongation step temperature, wherein the PCR amplification of the second amplification stage is conducted under different reaction condition than the PCR amplification of the first amplification stage. Durmaz further teaches wherein the first and second stages are conducted sequentially in the same reaction vessel (page 71, col. 1, and section 2.4. *Amplification*) Therefore, Durmaz et al meet the limitations of the claims of the instant invention.

Conclusion

7. Claims 1, 2, 7, 9, 14, 18, 28, 30, 32, 33, 41, 42 and 46 have been rejected. Claims 3, 4, 6, 8, 10-17, 19-27, 31, 34, 35, 37-40, 43-45, 47-53 are objected to because they depend from rejected claims. Claims 59-61, 63-66, 78-86 have not been rejected under prior art.

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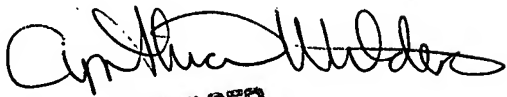
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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CYNTHIA WILDER
PATENT EXAMINER
2/6/05